**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| JEROME STEVENS PHARMACEUTICALS, INC., | | |
| Plaintiff, | Civil Action No.: | 02-1939 (RMU) |
| v. | Document No.: | 8 |
| FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND THE UNITED STATES OF AMERICA, | | |
| Defendants. | | |

**MEMORANDUM OPINION**

**GRANTING THE DEFENDANTS' MOTION TO DISMISS**

## I. INTRODUCTION

Plaintiff Jerome Stevens Pharmaceuticals, Inc. ("Jerome") is a small company that manufactures levothyroxine sodium ("LS") tablets under the name of Unithroid. Jerome brings suit against the Food and Drug Administration ("FDA"), Department of Health and Human Services ("HHS"), and United States (collectively, "the defendants"[1]) alleging violations of the Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§ 1346(b), 2671-2680; Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq.*; and Fifth Amendment to the Constitution. The defendants moved to dismiss Jerome's claims pursuant to Federal Rules of Civil Procedure 12(b)(1) and (6). Because the court lacks subject-matter jurisdiction under the FTCA, the APA and the Constitution, the court grants the defendants' motion to dismiss.

[1] Only the United States may be a defendant for an FTCA claim. 28 U.S.C. §§ 1346(b), 2679(a); *Seitu v. Rutherford*, 1997 WL 122919, at *1 (D.D.C. Mar. 12, 1997). Because Jerome's suit involves non-FTCA claims as well, the court refers to "the defendants" rather than to the United States when discussing both the FTCA and non-FTCA claims.

## II. BACKGROUND

### A. Background

Since the 1950s, physicians have prescribed LS tablets for the treatment of thyroid diseases. Compl. ¶ 8. In August 1997, however, FDA issued a notice that new information had shown significant stability and potency problems with currently marketed LS products, and that this lack of stability and consistent potency had the potential to cause serious public-health consequences. *Id.* ¶¶ 15-16 (citing 62 FED. REG. 43535 (Aug. 14, 1997)). Accordingly, notwithstanding the history of LS use, FDA announced that orally administered LS products were "new drugs," and that manufacturers wishing to continue marketing LS products would have to submit New Drug Applications ("NDAs") for FDA approval by August 14, 2000 or be subject to adverse regulatory action. *Id.* ¶¶ 14, 17.

FDA initially set a deadline of August 14, 2000 for the NDA approval date. *Id.* ¶ 17. In April 2000, however, a few months prior to the deadline, FDA extended the deadline by one year, to August 14, 2001. *Id.* ¶ 29 (citing 65 FED. REG. 24488 (Apr. 26, 2000)). On August 21, 2000, FDA approved Jerome's NDA, making Jerome's Unithroid the first LS drug approved under the new requirements. *Id.* ¶ 30.

One day after the approval, FDA posted on its website information that, according to Jerome, contained Jerome's confidential and trade-secret information for Unithroid ("the Jerome information").[2] *Id.* ¶ 31. Jerome discovered this disclosure about four months later. *Id.* ¶ 35. Jerome then notified FDA of the disclosure and demanded that FDA remove the Jerome information from its website. *Id.* ¶¶ 35-37. FDA removed some of the Jerome information on

[2] Jerome describes the trade secrets at issue as "[t]he order in which Unithroid's ingredients are added together; the steps that the additions go through in the formation of Unithroid's tablets; and the processing of the active ingredient, levothyroxine sodium." Compl. ¶ 67. The court makes no statement as to whether the Jerome information qualifies as trade secrets or confidential information.

January 12, 2001, and, after receiving additional calls from Jerome, removed the remaining information on January 23, 2001. *Id.* ¶¶ 38-41.

Meanwhile, in May 2001, FDA approved the NDA for Levoxyl, a competing LS drug manufactured by Jones Pharma. *Id.* ¶¶ 51-52. Jones Pharma's Levoxyl thereby became the second LS drug approved prior to the August 2001 deadline. *Id.* No other LS drugs – including Synthroid, Abbott Laboratories' LS drug that traditionally dominated the market – received NDA approval prior to the August 2001 deadline.[3] *Id.* ¶¶ 54-65.

In July 2001, one month before the August 2001 deadline, FDA announced that it was "continu[ing] to exercise its enforcement discretion by establishing a gradual phase-out of unapproved [LS] products." *Id.* ¶ 44 (quoting 66 FED. REG. 36794 (July 13, 2001)). Specifically, FDA stated that those LS manufacturers who filed but did not receive approval for an NDA ("the non-approved manufacturers") before the August 2001 deadline could nonetheless continue marketing their LS products for another two years through August 2003, although they had to gradually phase out distribution during that period.[4] *Id.* ¶¶ 44-45. Jerome reports that after FDA's announcement, Abbott Laboratories "flooded the retail market with mass quantities of its then unstable LS drug product [Synthroid]." *Id.* ¶ 47. Having lost *de facto* market exclusivity "due to FDA's publication of its secrets and FDA's extensions of compliance

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[3] Other LS manufacturers received approval for their LS drugs after the August 2001 deadline. Mova Pharmaceutical Corporation received NDA approval for Levo-T in March 2002. Compl. ¶¶ 54-55. Genpharm received NDA approval for Novothyrox in May 2002. *Id.* ¶¶ 57-58. Mylan Pharmaceuticals, Inc., received abbreviated NDA approval in June 2002. *Id.* ¶¶ 60-61. Abbott Laboratories received NDA approval for Synthroid in July 2002. *Id.* ¶¶ 54-55. Lloyd Inc. received NDA approval for Thyro-Tabs in October 2002. Defs.' Mot. to Dismiss at 7.

[4] FDA indicated that LS manufacturers who did not have an NDA pending by August 14, 2001 would have to cease distribution of their products immediately or else be subject to regulatory action. 66 FED. REG. 36794 (citing Guidance for Industry: Levothyroxine Sodium Products – Enforcement of August 14, 2001, Compliance Date and Submission of New Applications, available at www.fda.gov/cder/guidance/index/htm).

deadlines," Jerome laid off 22 employees hired to supply the previously anticipated demand for Unithroid, and Jerome's partner Watson Laboratories destroyed drums of Unithroid valued at up to $33 million. *Id.* ¶ 48.

Jerome subsequently filed a six-count complaint in this court.[5] *Id.* ¶¶ 66-117. Counts one and two ("the tort claims") allege that the defendants misappropriated Jerome's trade secrets and breached a confidential relationship by disclosing the Jerome information via FDA's website. *Id.* ¶¶ 66-86. Counts three and four ("the constitutional claims") assert that the defendants violated Jerome's procedural and substantive due-process Fifth Amendment rights by disclosing the Jerome information. *Id.* ¶¶ 87-97. Finally, count five ("the APA disclosure claim") and count six ("the APA deadline-extension claim") allege that the defendants' failure to guard against disclosure of the Jerome information and granting of the deadline extensions[6] qualify as arbitrary and capricious under the APA. *Id.* ¶¶ 98-117. For relief, Jerome seeks compensatory damages of more than $1.3 billion for the tort claims and declaratory relief for the remaining claims. *Id.* ¶¶ 118-24. In response, the defendants moved to dismiss for lack of subject-matter jurisdiction and failure to state a claim on which relief may be granted. The court now addresses the defendants' motion to dismiss.

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[5] Prior to filing suit, Jerome exhausted its FTCA claims by presenting its claims to FDA and failing to receive a final agency disposition within six months. Compl. ¶¶ 49-50; 28 U.S.C. § 2675(a).

[6] Jerome challenges both (1) the FDA's April 2000 action extending the original August 14, 2000 deadline to August 14, 2001 and (2) the FDA's July 2001 action permitting non-approved manufacturers to gradually phase out their LS products by August 14, 2003 ("the deadline extensions"). Compl. ¶¶ 112, 122. The court notes, however, that Jerome itself benefitted from the first extension, as Jerome's Unithroid did not win FDA approval until one week after the original August 14, 2000 deadline. *Id.* ¶ 30 (stating that Jerome received FDA approval for Unithroid on August 21, 2000). Nonetheless, because Jerome explicitly challenges both deadline extensions, the court proceeds accordingly.

## III. ANALYSIS

### A. Legal Standard for a Motion to Dismiss Pursuant to Rule 12(b)(1)

Federal courts are courts of limited jurisdiction and the law presumes that "a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *St. Paul Mercury Indem. Co. v. Red Cab Co.*, 303 U.S. 283, 288-89 (1938); *see also Gen. Motors Corp. v. Envtl. Prot. Agency*, 363 F.3d 442, 448 (D.C. Cir. 2004) (noting that "[a]s a court of limited jurisdiction, we begin, and end, with an examination of our jurisdiction").

Because "subject-matter jurisdiction is an 'Art. III as well as a statutory requirement[,] no action of the parties can confer subject-matter jurisdiction upon a federal court.'" *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003) (quoting *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxite de Guinea*, 456 U.S. 694, 702 (1982)). On a motion to dismiss for lack of subject-matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff bears the burden of establishing that the court has subject-matter jurisdiction. *Evans v. B.F. Perkins Co.*, 166 F.3d 642, 647 (4th Cir. 1999); *Rasul v. Bush*, 215 F. Supp. 2d 55, 61 (D.D.C. 2002) (citing *McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 182-83 (1936)). The court may dismiss a complaint for lack of subject-matter jurisdiction only if "'it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" *Empagran S.A. v. F. Hoffman-Laroche, Ltd.*, 315 F.3d 338, 343 (D.C. Cir. 2003) (quoting *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957)).

Because subject-matter jurisdiction focuses on the court's power to hear the claim, however, the court must give the plaintiff's factual allegations closer scrutiny when resolving a Rule 12(b)(1) motion than would be required for a Rule 12(b)(6) motion for failure to state a claim. *Macharia v. United States*, 334 F.3d 61, 64, 69 (D.C. Cir. 2003); *Grand Lodge of*

*Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 9, 13 (D.D.C. 2001). Moreover, the court is not limited to the allegations contained in the complaint. *Hohri v. United States*, 782 F.2d 227, 241 (D.C. Cir. 1986), *vacated on other grounds*, 482 U.S. 64 (1987). Instead, to determine whether it has jurisdiction over the claim, the court may consider materials outside the pleadings. *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992).

**B. The Court Lacks Subject-Matter Jurisdiction Over Jerome's Tort Claims**

**1. The Federal Tort Claims Act**

The FTCA "grants federal district courts jurisdiction over claims arising from certain torts committed by federal employees in the scope of their employment, and waives the government's sovereign immunity from such claims." *Sloan v. Dep't of Housing & Urban Dev.*, 236 F.3d 756, 759 (D.C. Cir. 2001) (citing 28 U.S.C. §§ 1346(b) & 2674). To protect the government from liability "that would seriously handicap efficient government operations," the waiver of sovereign immunity is subject to several exceptions. *Beins v. United States*, 695 F.2d 591, 611 (D.C. Cir. 1982) (internal quotations omitted); 28 U.S.C. § 2680. If any one of the exceptions applies, the district court lacks subject-matter jurisdiction. 28 U.S.C. § 2680; *Sloan*, 236 F.3d at 759.

An oft-cited exception to the FTCA's sovereign-immunity waiver is the discretionary-function exception, which bars claims "based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused." 28 U.S.C. § 2680(a). To determine whether the discretionary-function exception applies, courts engage in a two-part inquiry. *Macharia*, 334 F.3d at 65 (citing *United States v. Gaubert*, 499 U.S. 315, 322-23 (1991)). First, the court must determine whether a federal statute, regulation, or policy

"specifically prescribes a course of action for an employee to follow . . . [leaving] the employee [] no rightful option but to adhere to the directive. *Id.* If so, the challenged action does not involve "an element of judgment or choice" and does not fall within the discretionary-function exception. *Id.* Second, the court must evaluate whether the challenged action "is of the kind that the discretionary function exception was designed to shield" from judicial second-guessing: namely, governmental actions and decisions based on public-policy considerations. *Id.* If the action is not grounded in public-policy concerns, it is not immunized by the discretionary-function exception. *Appleton v. United States*, 69 F. Supp. 2d 83, 92 (D.D.C. 1999).

Another FTCA exception is the intentional-torts exception, which provides that the United States retains sovereign immunity for any "claim[s] arising out of assault, battery, false arrest, malicious prosecution, abuse of process, libel, slander, misrepresentation, deceit or interference with contract rights." 28 U.S.C. § 2680(h). Given its "sweeping language," the exception excludes claims that sound in negligence but "aris[e] out of" an intentional tort. *Kugel v. United States*, 947 F.2d 1504, 1507 (D.C. Cir. 1991) (quoting *United States v. Shearer*, 473 U.S. 52, 55 (1985)). In interpreting the intentional-tort exception with regard to contract rights, the D.C. Circuit has concluded that the exception protects the government not only from claims of interference with existing contracts, but also from claims of interference with prospective economic advantage. *Art Metal-U.S.A., Inc. v. United States*, 753 F.2d 1151, 1155 (D.C. Cir. 1985).

To assure itself of subject-matter jurisdiction, the court must determine the basis for a plaintiff's FTCA claims, keeping in mind that "[a] litigant cannot circumvent the [FTCA] by the simple expedient of drafting in terms of negligence a complaint that in reality is a claim as to which the United States remains immunized." *Id.*, 753 F.2d at 1160 n.16 (quoting *Johnson v.*

*United States*, 547 F.2d 688, 691-92 (D.C. Cir. 1976)). Toward that end, the court "must review the complaint to determine what actions allegedly caused the injuries." *Cope v. Scott*, 45 F.3d 445, 448 (D.C. Cir. 1995) (applying the discretionary-function exception); *see also Kugel*, 947 F.2d at 1507 (noting in applying the intentional-tort exception that the court "must scrutinize the alleged cause of [an FTCA plaintiff's] injury"). Although the court must accept the plaintiff's version of the facts as true, the court need not accept "the plaintiff's *characterization* of the facts." *Fisher Bros. Sales, Inc. v. United States*, 46 F.3d 279, 286 (3d Cir. 1995) (emphasis in original); *see also Gen. Dynamics Corp. v. United States*, 139 F.3d 1280, 1283 (9th Cir. 1998) (citing *Fisher Bros.* with approval).

**2. The Defendants' Actions Fall Within the Discretionary-Function Exception**

The defendants assert that the discretionary-function exception bars Jerome from bringing its tort claims. Defs.' Mot. at 14-16. At the outset, the defendants argue that the tort claims stem not from the disclosure, but from the deadline extensions. *Id.* at 15; Defs.' Reply at 8. In support of their argument, the defendants point to the economic-loss analysis underlying Jerome's $1.3 billion damages request. Defs.' Mot. at 3 & Attach. 1; Defs.' Reply at 8-9. Specifically, the defendants note that the analysis' damages estimate turns on the assumption that Jerome and Jones Pharma – the only other LS manufacturer to meet the August 2001 deadline – "would have split 90% of the market between them." *Id.* The defendants indicate, however, that deadline extensions allowed other LS manufacturers to retain their market share and consequently made it more difficult for Jerome to expand, thus causing Jerome's damages. Defs.' Reply at 9. Accordingly, the defendants conclude that the tort claims actually are based upon the deadline extensions, which they describe as "classically" discretionary decisions that fall within the discretionary-function exception. *Id.*; Defs.' Mot. at 14.

In response, Jerome insists that its tort claims "arise from the disclosure of its trade secrets and confidential communications [and that] disclosure was the tortious act that created the tortious injury." Pl.'s Opp'n at 27 (emphasis in original). Stating that the defendants are mischaracterizing its tort claims, Jerome asserts that its injury is not dependent on an increase in Jerome's market share and that in fact the deadline extensions are "totally irrelevant" to its tort claims. *Id.* at 17, 27 & n.21. According to Jerome, the disclosure does not qualify as a discretionary action because FDA has a mandatory legal obligation to protect trade secrets from disclosure. *Id.* at 9-10 (citing 5 U.S.C. § 552(b)(4), 18 U.S.C. § 1905, 21 U.S.C. § 331(j), and FDA regulations).

Jerome's arguments, however, collapse under the weight of their internal inconsistencies. The complaint states clearly that Jerome seeks more than $1.3 billion in damages for "injuries resulting from Defendants' misappropriation of Jerome's trade secrets and breach of FDA's confidential relationship with Jerome." Compl. ¶ 118. Yet the defendants correctly note that this damages figure derives from an economic-loss analysis whose first assumption is that Jerome and Jones Pharma would have dominated the LS market – an outcome possible only if FDA had not extended the August 2001 deadline to allow other LS manufacturers to remain in the market.[7] Defs.' Mot. Attach. 1. Moreover, Jerome acknowledges the impact of the deadline extensions when it states that it "lost de facto market exclusivity due to FDA's publication of its secrets *and* FDA's extension of compliance deadlines" and "in the months *following the July 2001 Guidance* [that permitted other LS manufacturers to remain in the market]" had to lay off employees and destroy drums of Unithroid. Compl. ¶ 48 (emphasis added).

[7] The economic-loss analysis consists of a report that Jerome submitted as part of its administrative claim for the alleged torts. Defs.' Mot. at 3 & Attach. 1; Pl.'s Opp'n at 17. Although the analysis is not contained in the complaint, the court may consider it to assist in its determination of subject-matter jurisdiction. *Hohri*, 782 F.2d at 241; *Herbert*, 974 F.2d at 197.

It appears, then, that the action causing Jerome's injury was not the disclosure, but rather the deadline extensions (and more specifically, the July 2001 extension[8]). *Id.*; *see Sloan*, 236 F.3d at 762 (determining that injuries alleged by public-housing subcontractors arose from federal housing officials' suspension of the subcontractors from government contracting and not from the officials' investigation into the subcontractors, as the subcontractors alleged); *Fisher*, 46 F.3d at 286 (concluding that injuries alleged by Chilean fruit-growers were caused by the FDA commissioner's decision to bar Chilean fruit and not by negligent FDA laboratory procedures, as the growers alleged). Moreover, even if the disclosure caused some degree of injury, Jerome does not "allege some harm arising from [the disclosure] that was separate from [the deadline extensions]," and thus any harm from the disclosure is not "sufficiently separable" from the deadline extensions to support suit under FTCA. *Sloan*, 236 F.3d at 762. Accordingly, the court treats Jerome's tort claims as "based upon" FDA's deadline extensions. *Id.*

The issue before the court, then, is whether the deadline extensions fall within the discretionary-function exception. The court concludes that they do. First, the act of extending the deadlines clearly involves "an element of judgment or choice." *Macharia*, 334 F.3d at 65. FDA issued the extensions pursuant to its authority under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, to regulate new drugs and address misbranded drugs. 62 FED. REG. 43535; 65 FED. REG. 24488; 66 FED. REG. 36794. Although the FDCA contains certain conditions with regard to the approval or disapproval of new drugs, it leaves to the HHS Secretary the decidedly judgment-based task of determining whether those conditions exist. 21 U.S.C. § 355(d) (setting forth the grounds for approving or refusing to approve NDAs); *Sloan*,

[8] See note 5, *supra*, regarding the one-week gap between the August 14, 2000 deadline and Unithroid's August 21, 2000 approval.

236 F.3d at 760 (noting that "determining whether [] broadly stated conditions exist involves substantial elements of judgment"). Moreover, the decision as to when and whether to take enforcement action against unapproved drugs qualifies as discretionary. *Sloan*, 236 F.3d at 760 (indicating that "[t]he decision to initiate a prosecution has long been regarded as a classic discretionary function").

Second, FDA based the deadline extensions on public-policy considerations regarding the health needs of the millions of thyroid patients. *Macharia*, 334 F.3d at 65; *e.g.*, 66 FED. REG. 36794 (allowing manufacturers with pending NDAs to remain in the market because "it will take time for the millions of patients taking unapproved products to switch to approved products, and for manufacturers of approved products to scale up their production and to introduce this increased production into the distribution chain"). In light of the strong governmental focus on public health and safety that permeates the FDCA, "it must be presumed that [FDA's actions were] grounded in policy when exercising [its] discretion." *Sloan*, 236 F.3d at 761 (quoting *Gaubert*, 499 U.S. at 324); *e.g.*, 21 U.S.C. § 355(d). Because the deadline extensions fall within the discretionary-function exception, sovereign immunity bars Jerome's tort claims.[9] 28 U.S.C. § 2680(a); *Macharia*, 334 F.3d at 65. The court therefore grants the defendants' motion to dismiss the tort claims (counts one and two) for lack of subject-matter jurisdiction. *Sloan*, 236 F.3d at 759; 28 U.S.C. § 2680.

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[9] The intentional-torts exception also appears to bar the tort claims, as the claims arguably "arise out of" the defendants' alleged interference with the contract rights and prospective economic advantage of Jerome and its partner, Watson Laboratories. 28 U.S.C. § 2680(h); Compl. ¶ 48 (stating that "[h]aving lost de facto market exclusivity due to FDA's publication of its secrets and FDA's extensions of compliance deadlines, Jerome – in the months following the July 2001 Guidance – laid off all 22 people that it had hired to supply anticipated demand for [Unithroid and] . . . destroyed drums of Unithroid worth at retail an estimated $3 million to Jerome and $30 million to Watson Laboratories"); Defs.' Mot. Attach. 1 (indicating that Jerome's economic-loss analysis "is based in large part on a contract between [Jerome] and its partner, Watson Labs").

### C. The Court Lacks Subject-Matter Jurisdiction Over Jerome's Constitutional Claims and Jerome's APA Disclosure Claim

#### 1. Declaratory Judgments

Under the Declaratory Judgment Act, a court may declare the rights and other legal relations of any interested party "[i]n a case of actual controversy within its jurisdiction." 28 U.S.C. § 2201(a). "The term 'actual' is . . . one of emphasis, and not indicative of a different standard from Article III as to what qualifies as a controversy." *Fed. Express Corp. v. Air Line Pilots Ass'n*, 67 F.3d 961, 963 n.2 (D.C. Cir. 1995). "To satisfy the Constitution's case or controversy requirement, a party filing a declaratory judgment action must show that there is a controversy of 'sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 (D.C. Cir. 1998) (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). There must be "a real and substantial controversy admitting of specific relief through a decree of a conclusive character as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Fed. Express*, 67 F.3d at 963-64. If "an action has no continuing adverse impact and there is no effective relief that a court may grant, any request for judicial review of the action is moot." *Southwestern Bell Tel. Co. v. Fed. Communications Comm'n,* 168 F.3d 1344, 1350 (D.C. Cir. 1999). Even if a controversy exists, however, a district court has broad discretion to withhold declaratory judgment. *Wilton v. Seven Falls Co.*, 515 U.S. 277, 287 (1995) (noting "the unique breadth of [a district court's] discretion to decline to enter a declaratory judgment"); *Jackson v. Culinary Sch. of Wash., Ltd.*, 59 F.3d 254, 256 (D.C. Cir. 1995) (stating that the Supreme Court "took great pains to emphasize the singular breadth of the district court's discretion to withhold declaratory judgment").

**2. Jerome Has Not Shown a Controversy of Sufficient Immediacy and Reality**

Jerome seeks a declaratory judgment that in disclosing the Jerome information, the defendants violated Jerome's Fifth Amendment procedural and substantive due-process rights as well as the APA. Compl. ¶¶ 119-21. First, Jerome alleges that FDA violated its procedural due-process rights by failing to provide notice and an opportunity to be heard prior to disclosing the Jerome information. *Id.* ¶¶ 90-91; *see also* Pl.'s Opp'n at 3 (stating that the defendants failed to follow "the standard procedures FDA has in place to guard against public disclosure of NDA trade secrets and confidences"). Second, Jerome asserts that the disclosure was a deliberate and arbitrary abuse of government power that violated its substantive due-process rights. Compl. ¶¶ 96-97. Finally, Jerome contends that the disclosure was arbitrary, capricious, and contrary to law in violation of the APA. *Id.* ¶¶ 98-107. In Jerome's view, a declaratory judgment is appropriate because a controversy exists with regard to all three claims because the defendants' refusal to acknowledge the wrongfulness of the disclosure sets a precedent that threatens the integrity of the drug-approval process. Pl.'s Opp'n at 11. The defendants counter that the court should dismiss all three claims because FDA has approved Jerome's NDA and removed the Jerome information from its website, and as a result the judgment Jerome seeks would not redress a concrete injury but instead would constitute an advisory opinion. Defs.' Mot. at 28-30; Defs.' Reply at 3, 20.

The court concludes that Jerome has not shown a controversy of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Mova Pharm.*, 140 F.3d at 1073. Jerome does not allege that it will suffer a continuing adverse impact as a result of the alleged due-process and APA violations. *See generally* Compl.; Pl.'s Opp'n. Moreover, the precedential effect of an agency decision is not an injury sufficient to establish a controversy. *Am. Family Life Assurance Co. v. Fed. Communications Comm'n*, 129 F.3d 625, 629 (D.C. Cir. 1997); *see*

*also Radiofone, Inc. v. Fed. Communications Comm'n*, 759 F.2d 936, 939 (D.C. Cir. 1985) (declaring that a plaintiff's "injury must still arise from the particular activity which the agency adjudication has approved . . . and not from the mere precedential effect of the agency's rationale in later adjudications"). Accordingly, because the court finds that Jerome has not presented a controversy, the court grants the defendants' motion to dismiss the constitutional claims (counts three and four) and the APA disclosure claim (count five). *Mova Pharm.*, 140 F.3d at 1073.

### D. The Court Lacks Subject-Matter Jurisdiction Over Jerome's APA Deadline-Extension Claim

#### 1. The Administrative Procedure Act

The APA entitles "a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . to judicial review thereof." 5 U.S.C. § 702. Under the APA, a reviewing court must set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706; *Tourus Records, Inc. v. Drug Enforcement Admin.*, 259 F.3d 731, 736 (D.C. Cir. 2001). A court may not review an agency action, however, where "(1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." 5 U.S.C. § 701(a)(2); *Heckler v. Chaney*, 470 U.S. 821, 828 (1985). The APA's ban on judicial review of such actions is jurisdictional. *Balt. Gas & Elec. Co. v. Fed. Energy Regulatory Comm'n*, 252 F.3d 456, 459 (D.C. Cir. 2001) (holding that "[t]he ban on judicial review of actions 'committed to agency discretion by law' is jurisdictional"); *Patent Office Prof'l Ass'n v. Fed. Labor Relations Auth.*, 128 F.3d 751, 753 (D.C. Cir. 1997) (noting that the APA provides no jurisdiction when "statutes preclude judicial review").

"[A]n agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion." *Chaney*, 470 U.S.

at 831. This presumption of unreviewability applies because an agency decision not to enforce

> often involves a complicated balancing of a number of factors which are peculiarly within its expertise . . . including whether a violation has occurred, . . . whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all.

*Id.*; *see also Nat'l Wildlife Fed'n v. Envtl. Prot. Agency*, 980 F.2d 765, 772-73 (D.C. Cir. 1992) (quoting *id.*). Moreover, the agency "is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities." *Shell Oil Co. v. Envtl. Prot. Agency*, 950 F.2d 741, 764 (D.C. Cir. 1991) (quoting *Chaney*, 470 U.S. at 831-32). That said, the presumption may be overcome

> (1) where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers; (2) where the agency refuses to institute proceedings based solely on the belief that it lacks jurisdiction; and (3) where the agency has conspicuously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities.[10]

*Balt. Gas & Elec.,* 252 F.3d at 460 (quoting *Chaney*, 470 U.S. at 833 & n.4). Courts therefore must carefully examine the statute on which the claim is based. *Webster v. Doe*, 486 U.S 592, 600 (1988).

**2. The Deadline Extensions Are Not Reviewable**[11]

In its APA deadline-extension claim, Jerome seeks a declaratory judgment that the

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[10] "In *Chaney*, the Court endorsed only the first of these three exceptions but noted the possibility of the other two, 'express[ing] no opinion on whether such decisions would be unreviewable' but 'not[ing] that in those situations the statute conferring authority on the agency might indicate that such decisions were not 'committed to agency discretion.'" *Balt. Gas & Elec.*, 252 F.3d at 460 n.2 (quoting *Chaney*, 470 U.S. at 833 n.4).

[11] In contrast to the constitutional and APA disclosure claims, Jerome's APA deadline-extension claim presents a controversy, as FDA's July 2001 action permitted LS manufacturers other than Jerome and Jones Pharma to remain in the market past August 14, 2001, and therefore has a "continuing adverse impact" on Jerome. *Southwestern Bell*, 168 F.3d at 1350.

deadline extensions were arbitrary and capricious because they violated FDA's statutory duty to protect the public health. Compl. ¶¶ 108-117, 122. Specifically, Jerome contends that FDA acted arbitrarily, capriciously, and in violation of law when it extended the original deadline of August 14, 2000 to August 14, 2001 "without explaining how continued marketing of unapproved, unstable and unsafe LS drugs for another year served the public health interest" in light of Unithroid's approval.[12] *Id.* ¶ 112 (citing 21 U.S.C. §§ 355, 393). Jerome likewise contends that FDA acted arbitrarily, capriciously, and in violation of law when it permitted non-approved manufacturers to continue to market their LS products through August 14, 2003, again without explaining how that marketing served the public health interest in light of Unithroid's approval. *Id.* ¶ 113 (citing 21 U.S.C. §§ 355, 393). In Jerome's view, the deadline extensions departed from longstanding FDA policy and precedent, and amount to an abdication of FDA's statutory responsibility to protect the public from unsafe drugs. *Id.* ¶ 115; Pl.'s Opp'n at 31.

In response, the defendants contend that the deadline extensions are enforcement decisions "committed to agency discretion by law" and not subject to judicial review under the APA. Defs.' Mot. at 16, 19. According to the defendants, "[t]he entirety of FDA's decisions on this matter were an exercise of enforcement authority," as once FDA determined that LS products were new drugs it had the ability to direct manufacturers to remove all LS products from the market or face enforcement action. *Id.* at 19. The defendants state that here, "FDA chose not to take immediate enforcement action, and instead announced a grace period (which it then

[12] But see note 5, *supra*, regarding the one-week gap between the August 14, 2000 deadline and Unithroid's August 21, 2000 approval.

extended) during which it did not intend to take enforcement action."[13] *Id.* at 20. Furthermore, the defendants contend that FDA based its decisions not on judicially manageable standards, but on policy considerations such as the medical necessity of LS drugs, the time necessary for manufacturers to prepare NDAs, and the time required for millions of thyroid patients to switch from unapproved to approved LS drugs. *Id.* at 20-21. Finally, the defendants stress that the deadline extensions did not establish a general and permanent policy, but instead applied to a "small and finite group of manufacturers . . . for a limited period of time." Defs.' Reply at 16-17.

The court agrees with the defendants that here, the deadline extensions qualify as decisions not to prosecute or enforce, and therefore enjoy a presumption of unreviewability. *Chaney*, 470 U.S. at 831. Each of the deadline extension notices reflects the enforcement nature of FDA's actions. In its initial August 1997 notice, FDA indicated that it would permit existing LS drugs to be marketed through August 14, 2000, but that after that date such drugs would "be subject to regulatory action." 62 FED. REG. at 43538. In April 2000, FDA extended the "compliance date" through August 14, 2001. 65 FED. REG. at 24489. Finally, in July 2001, FDA indicated that it "ha[d] decided to continue to exercise its enforcement discretion by establishing a gradual phase-out of unapproved products" through August 14, 2003. 66 FED. REG. at 36794. Moreover, FDA based the deadline extensions on a balancing of factors that clearly fall within FDA's expertise, such as the medical necessity of LS drugs and the period of time needed to transition millions of patients safely from an unapproved- to an approved-drug system. *Chaney*, 470 U.S. at 831 (noting as an agency-expertise factor "whether the particular enforcement action

[13] The defendants contend that by failing to challenge FDA's August 1997 notice indicating that LS products were new drugs but allowing unapproved LS products to remain on the market through August 2000, Jerome "apparently concedes that FDA had the discretion to permit the marketing of unapproved LS products" from August 1997 to August 2000, a position the defendants believe is inconsistent with Jerome's challenge to the deadline extensions. Defs.' Reply at 14.

requested best fits the agency's overall policies"); *e.g.*, 66 FED. REG. at 36794 (explaining, *inter alia*, that "it will take time for millions of patients taking unapproved products to switch to approved products").

Having found that the deadline extensions are presumptively unreviewable, the court examines two FDCA provisions cited by Jerome to determine whether they overcome the presumption. *Chaney*, 470 U.S. at 832-33; *Webster*, 486 U.S at 600. At the outset, the court notes that under the FDCA's enforcement provisions, the HHS Secretary enjoys "complete discretion" to decide how and when to exercise enforcement authority. *Chaney* at 835 (citing 21 U.S.C. §§ 332, 334, & 372). Jerome argues, however, that FDA has a duty pursuant to sections 355 and 393(b) of the FDCA to promote and protect the public health by ensuring that human drugs are safe and effective. Compl. ¶ 114 (citing 21 U.S.C. 355 & 393(b)).

Neither provision, however, provides enforcement guidelines sufficient to overcome the presumption of unreviewability. *Chaney*, 470 U.S. at 832-33. Section 355 bars the introduction of new drugs without FDA-approved NDAs, and establishes a system for processing, approving, and withdrawing approval of NDAs. 21 U.S.C. § 355. But the Supreme Court has stated flatly that section 355 is "simply irrelevant to the agency's discretion to refuse to initiate [enforcement] proceedings." *Chaney* at 836; *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 676 (D.C. Cir. 1994) (reiterating *Chaney*'s conclusion). As for section 393, it sets forth FDA's mission statement, which among other things indicates that FDA "shall . . . promote the public health by ensuring that . . . drugs are safe and effective." *Id.* § 393(b)(2)(B). This broadly worded section does not address enforcement, however, and if anything only underscores FDA's authority to determine how best to ensure the safety and effectiveness of drugs. *Safe Energy Coalition v. Nuclear Regulatory Comm'n*, 866 F.2d 1473, 1478 (D.C. Cir. 1989) (concluding that statutory

provisions relating to the Nuclear Regulatory Commission's mandate to "protect health" did not displace the presumption of unreviewability of the Commission's actions because the provisions "[did] not provide any guidance to, let alone constrain, the agency in its efforts to 'protect health'").

Nor is this a case in which FDA has implemented a policy of non-enforcement that amounts to "an abdication of its statutory responsibilities."[14] *Balt. Gas & Elec.*, 252 F.3d at 460 (quoting Chaney, 470 U.S. at 833 & n.4). The deadline extensions do not constitute a permanent policy for all existing drug products for which the FDA has issued a new-drug notice, but rather were limited to non-approved manufacturers for a period of three years, and FDA retains the authority to meet its responsibilities. *Shell Oil*, 950 F.2d at 765 (concluding that an Environmental Protection Agency rule protecting permit-holders from enforcement actions for violations of a hazardous-waste statute was not an abdication of the agency's responsibilities because the rule's effect was limited both in scope and duration and EPA retained sufficient flexibility to carry out its responsibilities).

In short, the deadline extensions are agency non-enforcement decisions that enjoy a presumption of unreviewability, and Jerome has not rebutted that presumption.[15] *Chaney*, 410 U.S. at 831; *Balt. Gas & Elec.,* 252 F.3d at 460. Accordingly, the court grants the defendants' motion to dismiss the APA disclosure claim (count 6) for lack of subject-matter jurisdiction.

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[14] Neither party raises the second possible ground for rebutting the presumption of unreviewability: that FDA "refuse[d] to institute proceedings based solely on the belief that it lack[ed] jurisdiction." *Balt. Gas & Elec.*, 252 F.3d at 460 (quoting *Chaney*, 470 U.S. at 833 & n.4); *see generally* Compl.; Defs.' Mot.; Pl.'s Opp'n; Defs.' Reply.

[15] "That [Jerome] prefer[s] a different means of enforcement is irrelevant, for the very reason underlying the decision in [*Chaney*]: the agency alone, and neither a private party nor a court, is charged with the allocation of enforcement resources." *Block v. Sec. & Exch. Comm'n*, 50 F.3d 1078, 1094 (D.C. Cir. 1995).

*Balt. Gas & Elec.*, 252 F.3d at 459; *Patent Office Prof'l Ass'n*, 128 F.3d at 753.

## IV. CONCLUSION

For the foregoing reasons, the court grants the defendants' motion to dismiss. An order consistent with this Memorandum Opinion is separately and contemporaneously issued this 28th day of May, 2004.

RICARDO M. URBINA
United States District Judge